IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

CHRISTOPHER HAWKINS,	
Plaintiff,	**Case No. 2:11-cv-1037**
v.	**Judge Peter C. Economus**
MEDTRONIC, INC., *et al.*	**MEMORANDUM OPINION AND ORDER**
Defendants.	

Plaintiff Christopher Hawkins filed this action claiming that he was injured by a medical device made by Defendant Medtronic, Inc. A more detailed background is set forth in this Court's September 24, 2012 Opinion and Order (the "Order"), in which the Court granted in part Defendant's Motion to Dismiss, dismissing Claims Three, Five, and Six. The Court denied the motion as to Claim One (design and manufacturing defects), Claim Two (failure to warn), and Claim Four (breach of warranty). This matter is before the Court on Defendant's motion to certify the Order for interlocutory appeal, or alternatively to reconsider the Order. (Dkt. 33.) For the reasons that follow, Defendant's motion is **DENIED**.

For an order to be appropriate for interlocutory appeal, this Court must find that it "involves a controlling question of law as to which there is substantial ground for difference of opinion," and an immediate appeal "may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b).

I. Controlling Questions of Law

Defendant correctly asserts that the Order involves the controlling and potentially fully dispositive legal questions of federal preemption and adequacy of pleading. Plaintiff does not address this issue in his response.

II. Substantial Ground for Difference of Opinion

Defendant asserts that "the Order relies upon an interpretation of law that is contrary to the great weight of other authority while applying outdated and superseded legal standards that are not applicable in this case." (Reply 10.) Defendant apparently argues that the Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996), sets forth "outdated and superseded legal standards" because it was decided prior to *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009). Defendant makes two primary arguments: (A) that the "parallel claims" standard set forth in *Lohr* does not apply here and (B) that the pleading standard applied in *Lohr* no longer applies in light of *Twombly* and *Iqbal*. This Court cited each of those decisions in its Order, setting forth the relevant and applicable holdings, but it will nonetheless revisit them here.

A. Preemption Test

In *Lohr*, the Supreme Court held that the preemption provision of the Medical Device Amendments of 1976 ("MDA"), contained in 21 U.S.C. § 360k(a), "simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Lohr*, 518 U.S. at 491. The device at issue in *Lohr* was approved through the "§ 510(k) process," which bypassed the more rigorous process known as "premarket approval" or "PMA." As the Supreme Court summarized in *Riegel*, the *Lohr* Court "rejected the . . . contention that § 510(k) approval imposed device-specific 'requirements.'" *Riegel*, 552 U.S. at 322.

In *Riegel*, the Court more explicitly set forth the test to determine whether a state requirement is pre-empted. Consistent with its analysis in *Lohr*, the Court held that it first "must determine whether the Federal Government has established requirements applicable to" the device in question. *Riegel*, 552 U.S. at 321. While the Court had determined in *Lohr* that

§ 510(k) devices did not satisfy this first condition of preemption, it held in *Riegel* that the PMA process, "in contrast, imposes 'requirements' under the MDA as we interpreted it in *Lohr*." *Riegel*, 552 U.S. at 322. Thus, § 510(k) devices do not satisfy the first condition of preemption, but PMA devices automatically satisfy this first condition of the preemption test. *Riegel*, 552 U.S. at 322–23.

If the federal requirements satisfy the first condition, the Court "must then determine whether [the plaintiff's] common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Riegel*, 552 U.S. at 321–22 (quoting § 360k(a)). The Court notes that Defendant's motion to dismiss misrepresented the Supreme Court's holding in *Riegel*.[1] The *Riegel* Court in fact held that the state law "duties underlying negligence, strict-liability, and implied-warranty claims" were requirements subject to potential preemption. *See Riegel*, 552 U.S. at 327–28. However, the Court did not address whether such requirements in that case were "different from, or in addition to" the federal requirements, and therefore preempted, because the plaintiffs had not argued below that the state requirements were parallel to the federal requirements. *Id.* at 330.

Defendant focuses on the difference between *Lohr* and *Riegel*, specifically on the question of whether the device was approved under § 510(k) or the PMA process. This difference is most obviously relevant to the first condition of preemption, which Defendant correctly concedes is satisfied. (Dkt. 16-1 at 4 ("Claims involving a PMA-approved device automatically satisfy [this] first condition of the preemption test.").)

[1] As this Court noted in its Order, "[a]ccording to Defendant, the *Riegel* Court held that 'the MDA pre-empt[s] claims of . . . breach of implied warranty.' (Dkt. 16-1 at 10 (quoting *Riegel*, 552 U.S. at 320–21).) Defendant again takes a quote out of context; the *Riegel* Court was merely stating the lower court's ruling."

Because this case involves a PMA device, automatically satisfying the first prong of the test, this second inquiry is the real focus of the Court's analysis: "whether [the plaintiff's] common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Riegel*, 552 U.S. at 321–22 (quoting § 360k(a)). Defendant suggests that this Court applied an "outdated" "parallel claim" standard from *Lohr*, asserting that *Riegel* instead sets forth the standard applicable to PMA devices. However, as noted above, the only reason that the *Riegel* Court did not discuss whether the state requirements were different from, or parallel to, the federal requirements is that the plaintiffs in that case had not raised the issue below:

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements. *Lohr*, 518 U.S., at 495, 116 S.Ct. 2240; see also id., at 513, 116 S.Ct. 2240 (O'Connor, J., concurring in part and dissenting in part). . . . Although the Riegels now argue that their lawsuit raises parallel claims, they made no such contention in their briefs before the Second Circuit, nor did they raise this argument in their petition for certiorari. We decline to address that argument in the first instance here.

Riegel, 552 U.S. at 330 (emphasis added). The *Riegel* Court did not change the character of the second inquiry set forth in *Lohr*—what Defendant refers to as the "parallel claims" test. Considering that that the *Riegel* Court explicitly declined to reach the issue as a procedural matter, it is difficult to understand any possible basis for Defendant's argument that *Riegel* changed the standard.

B. Pleading Standard

In *Lohr*, the Supreme Court held:

> Although the precise contours of their theory of recovery have not yet been defined (the pre-emption issue was decided on the basis of the pleadings), it is clear that the Lohrs' allegations may include claims that Medtronic has, to the extent that they exist, violated FDA regulations. At least these claims, they suggest, can be maintained without being pre-empted by § 360k, and we agree.

Lohr, 518 U.S. at 495. Defendant correctly points out that *Lohr* (decided in 1996) was decided before *Twombly* and *Iqbal* (decided in 2007 and 2009, respectively). This Court finds that *Lohr* can be applied consistent with *Twombly* and *Iqbal*, however, and again notes its agreement with the Western District of Kentucky that:

> In the context of MDA preemption, *Twombly* and *Iqbal* make a plaintiff's job more difficult than it would be in a typical product liability case. When facing MDA preemption, a plausible cause of action requires, among other things, a showing that the alleged violation of state law parallels a violation of federal law. This additional step requires some greater specificity in the pleadings. However, our appellate courts have been unable to agree upon the precise level of that specificity. Nonetheless, . . . a plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do."

White v. Stryker Corp., 818 F. Supp. 2d 1032, 1037 (W.D. Ky. March 25, 2011) (quoting *Twombly*, 550 U.S. at 555) (emphasis added).

There may be room for disagreement as to the precise level of specificity required by *Twombly* and *Iqbal*. However, the Court finds that Plaintiff has met the level of specificity which reasonably may be expected prior to discovery, and which is both consistent with *Lohr* and is sufficient "to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570).

III. Advancement of Litigation

Defendant asserts that "an appeal would materially advance this litigation because it has the potential to ultimately terminate and resolve this action prior to the parties engaging in costly and lengthy discovery, retaining experts, filing dispositive motions and proceeding to a jury trial." (Mot. 11.) Plaintiff, on the other hand, seeks "the opportunity to investigate why" Defendant's device malfunctioned and asserts that Defendant merely "seeks a second chance to avoid engaging in any discovery." (Resp. 2, 3.) If the Court believed that an interlocutory appeal would likely result in this case's dismissal, this factor would weigh in favor of Defendant. For the reasons discussed above, however, an appeal is unlikely to materially advance this litigation, but would rather likely delay it unnecessarily.

IV. Conclusion

As discussed above, the Order involves controlling and potentially fully dispositive legal questions. While there is some room for debate as to the applicable legal standards, the Order is based on controlling Supreme Court precedent, and this Court does not believe that the ground for difference of opinion is substantial enough to warrant an interlocutory appeal. Such an appeal would not, in this Court's opinion, be likely to materially advance this litigation. For these reasons, Defendant's Motion is **DENIED**. (Dkt. 33.)

IT IS SO ORDERED.

/s/ Peter C. Economus
UNITED STATES DISTRICT JUDGE